Clinical Trials Management Systems Workspace
Face-to-Face Meeting
Oregon Health & Science University

SESSION: Clinical Trial Application Functionality Demonstration

Session Information	**Date: May 30, 2007** **Time: 9:45 a.m.–10:45 a.m. PDT** **Presenter/Lead: Peter Covitz opened; Christo Andonyadis and John Speakman drove the demo** **Facilitator: Niket Parikh** **Scribe: Karen Ryan**
Executive Summary	A live demonstration was provided of some of the applications available in the Workspace (i.e., Cancer Central Clinical Participant Registry [C3PR], Cancer Central Clinical Database [C3D], cancer Adverse Event Reporting System [caAERS], Clinical Trials Object Model [CTOM] Lab Viewer, and Patient Study Calendar). The demonstration was not intended to showcase the latest view of the individual applications but rather their ability to interoperate during realistic scenarios of clinical trials workflow. Specific application-level functionality would be discussed in the deep-dive sessions the next day.
Discussion	The demonstration was well received and generated discussion on topics including patient identifiers, organization identifiers, laboratory test viewers and the need for a centralized protocols management tool.
Requirements	

Req. #	Name	Description

Issues

Issue ID	Description
1	A question was raised regarding which patient identifiers are stored for a study participant and how patients are tracked between applications. It was confirmed that any number of identifiers can be used within C3PR, but a system-generated patient ID is used to track patients between applications and studies.
2	Earlier working group discussion had recommended use of an authoritative Organization ID across institutions. However, implementation of this recommendation would require agreement beyond the National Cancer Institute (NCI) community.
3	CTOM Lab Viewer functionality that allows the user to view all laboratory tests in a given time frame is helpful. The ability to apply a filter to view only the test types specified by the protocol would also be useful because usually, clinical chemistry laboratory systems reports do not differentiate between tests carried out for clinical trials and tests that are part of the standard of care. This information would also be required by a clinical trials financial/billing system. The types of tests, as opposed to the actual instances of the tests, required by the protocol, could be stored and used to create a filter. This information could come from the Protocol Lifecycle Tracking (PLT) system.
4	The question was raised whether the Lab View uses Logical Observations Identifiers, Names, and Codes (LOINC). It was reported that developers are looking into this possibility, but the analysis is not yet complete.

5	Some human factor/usability issues concerning the use of color were raised. For example, the CTOM Lab Viewer uses black text on a red background to highlight laboratory values that may indicate potential adverse events. (This is usually legible onscreen but would not be if printed out on a black and white printer, and is not Section 508 compliant). More broadly, user interface issues across the CTMS domain have not been given the attention they deserve. This was noted as an issue for further discussion.
6	The need for a centralized protocols management tool was raised. It should be a service callable by any application to capture protocol information, preventing duplication of effort both by developers and users.
7	The need for Standard Operating Procedures (SOP) for regulatory compliance (for example, the Food and Drug Administration's [FDA] 21 CFR Part 11) was noted. It was further noted that the C3PR User Group has developed some SOPs, but that recent FDA guidance suggest that appropriate SOPs would be defined more precisely by FDA henceforth.

Action Items

Assigned To	Description	Due Date
CTMS Leadership	Develop a plan for user interface harmonization across CTMS	Next F2F
CTMS Leadership	Develop a plan for centralized protocol management across CTMS	Next F2F

Attendance

#	First Name	Last Name	Affiliation
1.	Christo	Andonyadis	NCI CBIIT
2.	Robert	Annechiarico	Duke University
3.	Rhoda	Arzoomanian	Univ of Wisconsin
4.	Steve	Barnard	Intel
5.	Greg	Bielawski	Patient Advocate
6.	John	Brandt	UNM CRTC
7.	Elaine	Brock	Univ of Michigan
8.	Troy	Budd	NCI / DCP
9.	Ram	Chilukuri	Semantic Bits
10.	Deborah	Collyar	Patient Advocate
11.	Don	Connelly	Univ of Minnesota CC
12.	Paul	Courtney	Dartmouth College
13.	Peter	Covitz	NCI CBIIT

14.	Leslie	Derr	NCI CBIIT
15.	Sharon	Elcombe	Mayo Clinic
16.	Douglas	Fridsma	Univ. of Pittsburgh
17.	Steve	Friedman	NCI CTEP
18.	Amy	Funkhouser	ECOG
19.	Allison	Geer	Velos, Inc.
20.	Lakshmi	Grama	NCI / OCE
21.	Meg	Gronvall	Booz Allen Hamilton
22.	Sonja	Hamilton	Mayo Clinic
23.	Smita	Hastak	ScenPro
24.	Virginia	Hetrick	Patient Advocate
25.	Kim	Johnson	CALGB
26.	Warren	Kibbe	Northwestern
27.	Bob	Lanese	Case
28.	Jieping	Li	Georgetown
29.	Jack	London	Jefferson-Kimmel CC
30.	David	Loose	BLCPro
31.	Brenda	Maeske	SAIC
32.	Jomol	Mathew	Dana-Farber
33.	Patrick	McConnell	Duke University
34.	Randy	Millikan	MD Anderson
35.	Bob	Morrell	WFU
36.	Sorena	Nadaf	Vanderbilt
37.	Joyce	Niland	City of Hope
38.	Rachel	Nosowsky	Univ of Michigan
39.	Susan	Pannoni	City of Hope
40.	Niket	Parikh	Booz Allen Hamilton
41.	Wendy	Patterson	NCI Technology Transfer Center
42.	Kerri	Phillips	PercipEnz

43.	Gopi	Potnuru	PercipEnz
44.	George	Redmond	NCI / CTEP
45.	Dianne	Reeves	NCI CBIIT
46.	Karen	Ryan	Booz Allen Hamilton
47.	Peter	Schad	NCI DCCPS
48.	Linda	Schmandt	Univ of Pittsburgh
49.	Angela	Smith	SWOG
50.	John	Speakman	NCI CBIIT
51.	Terri	Stewart	UNM CRTC
52.	Rhett	Sutphin	Northwestern
53.	Umit	Topaloglu	UAMS
54.	Troy	Walls	Univ of Arkansas
55.	Sean	Whitaker	Northwestern
56.	Julie	Zhu	Northwestern